

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

In re:

PharmaStem Therapeutics, Inc. Patent Litigation

MDL Docket No. 05-MD-1660-GMS

**DEFENDANTS' BRIEF PURSUANT TO
THE COURT'S PRACTICE AND PROCEDURE
ORDER FOR THE INITIAL PRETRIAL CONFERENCE**

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Pursuant to the Court's July 19, 2005 Practice and Procedure Order, ViaCell, Inc., Obstetrical and Gynecological Associates, P A., FemPartners, Inc., Caritas St Elizabeth's Medical Center of Boston, Inc., Cryo-Cell International, Inc., CorCell, Inc., Bruce Zafran, M D., Molly McBride, M D., Carlo M. Croce, M D., CBR Systems, Inc., Sutter Health, Inc., Monica Aszterbaum, M D., Andrew Cassidenti, M D., Eunice U. Lee, M D., Carla Wells, M D., Anita York, M D., Bruce A. Hagadorn, M D., Rafasree T. Seshadri, M D., and Arthur Goldstein, M D. collectively submit the following brief in preparation for the October 6, 2005 pretrial conference in the above-captioned matter:

A. Legal and Factual Background of the Case

The five cases transferred to this Court by the Multidistrict Litigation Panel are the second wave of litigation brought by PharmaStem Therapeutics, Inc. ("PharmaStem") alleging infringement of its patents. In addition, the related Delaware action already before this Court, *ViaCell, Inc., et al., v. PharmaStem Therapeutics, Inc.*, C.A. No. 04-1335 (GMS), has been consolidated with the transferred cases. Each of these cases involves patents derived from a single parent application, serial no. 07/119,746, filed November 12, 1987. The patents at issue include U.S. Patent Nos. 5,004,681 ("the '681 patent"), 5,192,553 ("the '553 patent"), 6,569,427 ("the '427 patent"), and 6,461,645 ("the '645 patent"). In general, these patents relate to compositions and methods involving the preservation of stem cells derived from human umbilical cord blood and therapeutic uses of such cells. The Court is already very familiar with the '681 composition patent and the '553 method patent, which were litigated and tried to a jury in the original Delaware action described below. The claims of the '645 composition patent are nearly identical to the claims of the '681 patent, particularly in that they both require stem cells in an "amount sufficient to effect hematopoietic reconstitution of a human adult." In addition,

most of the claims of the '427 method patent are nearly identical to the claims of the '553 patent, particularly in that they both require injection into a human. Claims 49-56 of the '427 patent are also very similar to the '681 patent in that they also require stem cells in an "amount sufficient to effect hematopoietic reconstitution of a human adult." The specifications of each patent are also substantially identical. PharmaStem's initial wave of litigation is currently on appeal before the Federal Circuit Court of Appeals ("Federal Circuit") where the infringement and validity of the '681 and '553 patents will be considered.

The background and posture of the consolidated cases are set forth below. As the Court will see, the key points raised by defendants are (1) the appeal of the original Delaware action is currently being briefed for the Federal Circuit Court of Appeals and (2) the two patents at issue in PharmaStem's second wave of litigation – the '427 and '645 patents – as well as the '553 patent, are currently in reexamination before the United States Patent and Trademark Office ("PTO"). Accordingly, defendants believe that any action in the cases now before the Court should be stayed pending a ruling from the Federal Circuit and the PTO since those decisions will have a material and substantial impact on the issues involved in the consolidated cases, and indeed may eliminate the need for any further action in these cases.

(1) The Original Delaware Action – The First Wave of Litigation

As the Court is aware, in February 2002 PharmaStem initiated litigation in the District of Delaware against private cord blood banks who refused to license PharmaStem's patents. PharmaStem filed suit against, *inter alia*, ViaCell, Inc. ("ViaCell"), Cryo-Cell International, Inc. ("Cryo-Cell"), CorCell, Inc. ("CorCell"), and CBR Systems, Inc. ("CBR"), alleging infringement of the '681 and '553 patents. *PharmaStem Therapeutics, Inc. v. ViaCell, Inc., et al*, C.A. No. 02-148-GMS (the "Delaware Action"). The case went to trial before a jury in October 2003 and the

jury returned its verdict in favor of PharmaStem, finding that the '681 patent and the '553 patent were valid and that the defendants had infringed both patents. On September 15, 2004, the Court ruled on the parties' post-trial motions finding, *inter alia*, that defendants were entitled to judgment as a matter of law regarding the '553 patent and that defendants were entitled to a new trial regarding the alleged infringement of the '681 patent.

On September 29, 2004, defendants filed a motion for partial reconsideration of the Court's post-trial rulings, requesting that the Court also enter judgment as a matter of law in favor of defendants regarding the alleged infringement of the '681 patent. The Court granted the relief requested by defendants on December 14, 2004, finding that PharmaStem had failed to present sufficient legal evidence of infringement of the '681 patent. Thus, defendants were found to not have infringed either the '681 or the '553 patent.

On January 6, 2005, PharmaStem appealed the Court's September 15, 2004 and December 14, 2004 decisions to the Federal Circuit. In response, the defendants filed a notice of cross-appeal. The procedural issues with respect to the appeal have now been worked out, and briefing has commenced in the Federal Circuit. PharmaStem filed its initial appellate brief on September 16, 2005 and the defendants' initial response brief is due October 31, 2005.

(2) Transferred Actions

In July and August 2004, PharmaStem initiated a second wave of litigation, this time targeting individual physicians, medical groups, and/or healthcare facilities in addition to the private umbilical cord banks that refused to license PharmaStem's patents. PharmaStem filed five new actions in separate district courts alleging infringement of the '427 and '645 patents, and in one case, asserting the '681 patent. *See PharmaStem Therapeutics, Inc. v. Cord Blood Registry, Inc., et al*, C A No. C-04-3072-JSW (N D Cal) (the "Northern California Action")

(asserting infringement of the '427 and '645 patents); *PharmaStem Therapeutics, Inc. v. CureSource, Inc., et al.*, C.A. No. SA-CV-04-921-GLT (C.C. Cal.) (the "Central California Action") (asserting infringement of the '681, '427, and '645 patents); *PharmaStem Therapeutics, Inc. v. CorCell, Inc., et al.*, C.A. No. 2:04-CV-03561-RK (the "Pennsylvania Action") (asserting infringement of the '427 and '645 patents); *PharmaStem Therapeutics, Inc. v. CryoCell International, Inc., et al.*, C.A. No. 8:04-CV-1740-T-30TGW (M.D. Fla.) (the "Florida Action") (asserting infringement of the '427 and '645 patents); and *PharmaStem Therapeutics, Inc. v. ViaCell, Inc., et al.*, C.A. No. 04-CV-11673-RWZ (D. Mass.) (the "Massachusetts Action") (asserting infringement of the '427 and '645 patents)

(3) Defendants' Claims Based Upon Conduct Directed at Obstetricians

As the Court is also aware, while post-trial motions were pending in the original Delaware Action in 2004, PharmaStem made false and misleading statements in an effort to dissuade obstetricians from collecting umbilical cord blood for their patients who were customers of defendants. In response, ViaCell filed a separate action against PharmaStem in the District of Delaware on October 5, 2004, asserting claims of antitrust and Lanham Act violations as well as claims for tortious interference and unfair and deceptive trade practices arising from PharmaStem's efforts to require obstetricians to sign "Amnesty Agreements" and agree to refrain from conduct that is beyond the scope of PharmaStem's patents as a condition of avoiding suit for infringement. *ViaCell, Inc. v. PharmaStem Therapeutics, Inc.*, C.A. 04-1335-GMS (D. Del.). CorCell and Cryo-Cell were joined as plaintiffs to this action by an amended complaint. Specifically the "Amnesty Agreements"¹ PharmaStem was encouraging physicians and hospitals

¹ PharmaStem's "Amnesty Agreement Program" involved PharmaStem's efforts to have physicians and hospitals sign an "Amnesty Agreement" in which PharmaStem agreed to drop all

to sign purport to prohibit obstetricians from the mere collection of cord blood despite the fact that no claim of any PharmaStem patent is directly or indirectly infringed by mere collection. As a result, ViaCell filed a motion for preliminary injunction to enjoin PharmaStem from continuing to make false and misleading statements and from enforcing its Amnesty Agreements. The parties thereafter, with the Court's assistance, resolved the issue by agreement; the agreement included, *inter alia*, termination of PharmaStem's Amnesty Program.

The defendants² then jointly filed a motion for consolidation and coordination of all of these cases for pretrial proceedings before Judge Sleet in Delaware on October 28, 2004. The Judicial Panel granted the motion on February 17, 2005 and the six cases (the five transferred cases and the case currently before the Court) were consolidated before this Court.

B. Procedural Status of the Consolidated Cases

(1) *PharmaStem Therapeutics, Inc. v. Cord Blood Registry, Inc., et al.*, C.A. No. C-04-3072-JSW, filed July 28, 2004, transferred from the Northern District of California. In addition to CBR,³ Sutter Health, Inc. ("Sutter Health"), a not-for-profit public benefit corporation, is also a defendant in this case. CBR and Sutter Health are alleged generally to "infringe, contributorily infringe and/or induce the infringement of the '427 patent," and CBR alone is alleged generally to "infringe, contributorily infringe and/or induce the infringement of the '645 patent." CBR and Sutter Health have answered and asserted a counterclaim against PharmaStem, PharmaStem's CEO, Nicholas Didier ("Mr. Didier"), Stembank, Inc.

claims and/or not to file suit if the physician or hospital agreed to a complete boycott of any private cord blood bank that has not signed one of PharmaStem's wrongful licenses.

² Despite the fact that PharmaStem is a defendant in the action brought by ViaCell, Cryo-Cell and CorCell, the term "defendants" as used herein refers to the defendants in all the actions brought by PharmaStem.

³ The legal name is CBR Systems Inc., and not Cord Blood Registry, Inc. as named in the complaint.

(“Stembanc”), and Stembanc’s CEO, Archibald Grabinski (“Mr. Grabinski”) for unfair competition, interference with contractual and business relationships, patent misuse, and deceptive and unfair trade practices. Mr. Didier has not yet responded to the counterclaims and Mr. Grabinski has been dismissed from the case. PharmaStem has served discovery requests in this action which have not yet been answered. No other discovery has been taken. PharmaStem’s motion for a preliminary injunction enjoining CBR from future infringement of the ‘645 and ‘427 patents is pending but was stayed and has not yet been fully briefed. The following motions, which have been fully briefed, are also pending:

1. PharmaStem’s motion to dismiss CBR’s counterclaims pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6); and
2. Stembanc’s motion to dismiss CBR’s counterclaims pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6)

(2) *PharmaStem Therapeutics, Inc. v. CureSource, Inc., et al.*, C.A. No. SA-CV-04-921-GLT, filed August 5, 2004, transferred from the Central District of California. The current defendants in this case include Monica Aszterbaum, M.D., Andrew Cassidenti, M.D., Eunice U. Lee, M.D., Carla Wells, M.D., Anita York, M.D., Bruce A. Hagadorn, M.D., Rafasree T. Seshadri, M.D., and Arthur Goldstein, M.D. CureSource, Inc. and three physician-defendants, Kathy Anderson, M.D., Charles W. Moniak, M.D., and Eliot Romero, M.D., have been dismissed from the action by PharmaStem pursuant to agreement. In addition, a default judgment has been entered against another physician, Nasrin Farbakhsh, M.D. The eight remaining physician-defendants are alleged generally to “infringe, contributorily infringe and/or induce the infringement of the ‘427 patent.” The physician-defendants have filed an answer and asserted counterclaims against PharmaStem for a declaration of non-infringement and invalidity of the ‘427 patent. PharmaStem has served discovery requests in this action which have not yet

been answered due to the stay in the case. No other discovery has been taken. There are no motions pending in this matter.

(3) *PharmaStem Therapeutics, Inc. v. CorCell, Inc., et al.*, C.A. No. 2:04-3561-RK, filed July 28, 2004, transferred from the Eastern District of Pennsylvania. In addition to CorCell, the defendants in this case are Molly McBride, M.D. and Carlo Croce, M.D. The physicians and CorCell are alleged generally to “infringe, contributorily infringe and/or induce the infringement of the ‘427 patent,” and CorCell alone is alleged generally to “infringe, contributorily infringe and/or induce the infringement of the ‘645 patent.” CorCell has asserted a counterclaim against PharmaStem and Mr. Didier for unfair competition, interference with contractual or other economic relationships, and trade libel/commercial disparagement. No discovery has been taken in this case, with the exception of a brief deposition of Dr. McBride in connection with her motion to dismiss for lack of personal jurisdiction. The following motions, all of which are fully briefed, are pending:

1. Motion of PharmaStem for entry of default judgment and entry of permanent injunction against Molly McBride, M.D. and Carlo Croce, M.D.;
2. Motion of Molly McBride, M.D. and Carlo Croce, M.D. to set aside entry of default;
3. Motion of Molly McBride, M.D. to dismiss for lack of personal jurisdiction under Rule 12(b)(2);
4. Motion of Nicholas Didier to dismiss counterclaim of CorCell under Fed. R. Civ. P. 12(b)(1), (2) and (6); and
5. Motion of PharmaStem to dismiss counterclaim of CorCell under Fed. R. Civ. P. 12(b)(6).

(4) *PharmaStem Therapeutics, Inc. v. Cryo-Cell International, Inc. et al.*, C.A. No. 8:04-1740-T-30TGW, filed July 28, 2004, transferred from the Middle District of Florida. In addition to Cryo-Cell, Bruce Zafran, M.D. is also named as a defendant. Dr. Zafran and Cryo-

Cell are alleged generally to “infringe, contributorily infringe and/or induce the infringement of the ‘427 patent,” and Cryo-Cell alone is alleged generally to “infringe, contributorily infringe and/or induce the infringement of the ‘645 patent.” Cryo-Cell has asserted a counterclaim against PharmaStem and Mr. Didier for unfair competition, interference with contractual and business relationships, patent misuse, and deceptive and unfair trade practices. Mr. Didier has not yet responded to the counterclaims. No discovery has been taken in this case. One motion, PharmaStem’s motion to dismiss Cryo-Cell’s counterclaim pursuant to Fed. R. Civ. P. 12(b)(6), has been fully briefed and is pending.

(5) *PharmaStem Therapeutics, Inc. v. ViaCell, Inc., et al.*, C.A. No. 04-CV-11673-RWZ (D. Mass.), filed July 28, 2004, transferred from the District of Massachusetts. In addition to ViaCell, Obstetrical and Gynecological Associates, P.A. (“OGA”), FemPartners, Inc. (“FemPartners”), and Caritas St. Elizabeth’s Medical Center of Boston, Inc. (“St. Elizabeth’s”) are also defendants in this case. Defendants are alleged generally to “infringe, contributorily infringe and/or induce the infringement of the ‘427 patent,” and ViaCell alone is alleged generally to “infringe, contributorily infringe and/or induce the infringement of the ‘645 patent.” Defendants answered the amended complaint on December 16, 2004 and have not yet filed any counterclaims. No discovery has been taken in this matter. One motion, PharmaStem’s motion for a preliminary injunction enjoining ViaCell from future infringement of the ‘645 and ‘427 patents, is pending but has not yet been fully briefed due to the stay in the case.

(6) *ViaCell, Inc., et al. v. PharmaStem Therapeutics, Inc.*, C.A. No. 04-1335-GMS, filed October 5, 2004, was already pending before this Court. In addition to ViaCell, Cryo-Cell and CorCell joined as plaintiffs in an amended complaint alleging claims of antitrust and Lanham Act violations by PharmaStem, as well as state law claims for tortious interference and

unfair and deceptive trade practices arising from PharmaStem's efforts to require obstetricians to agree to refrain from conduct that is beyond the scope of PharmaStem's patents as a condition for avoiding suit for infringement of those patents. Limited discovery was conducted regarding ViaCell's motion for preliminary injunction which was denied without prejudice. No other discovery has been taken. PharmaStem's motion to dismiss was denied without prejudice and as a result, PharmaStem must now answer the amended complaint. In addition, PharmaStem's motion to quash subpoena was also denied without prejudice and therefore, PharmaStem is now obligated to produce or permit inspection of the subpoenaed documents. There are no motions pending in this matter.

C. Critical Issues

(1) Infringement

In the transferred cases, PharmaStem generally alleges that the cord blood banks infringe the '645 and '427 patents and that the physicians and hospitals infringe the '427 patent. Individually and collectively however, PharmaStem's patents do not apply to the preservation of all cord blood or to all actions taken in connection with the collection and preservation of cord blood. The cord blood banks do not infringe for the same reasons previously litigated in the trial of the '681 and '553 patents. As to the hospitals and physicians, no claim of any PharmaStem patent covers the mere collection of cord blood. Thus, hospitals and/or physicians that collect cord blood, which a patient then provides to a private bank, do not infringe PharmaStem's patents. There is no direct infringement, because there is no evidence that physicians or hospitals meet all of the claimed elements of any one claim, in particular, they do not cryopreserve the cord blood. There is no contributory infringement, because (among other things) neither hospitals nor physicians nor the cord blood banks sell or offer to sell the cord

blood. There is no inducement to infringe, because there is no evidence that the physicians or hospitals or cord blood banks actively and knowingly aided and abetted another's direct infringement.

(2) Invalidity

In defense of PharmaStem's infringement allegations, defendants assert that the '645, '427, '681, and '553 patents are all invalid as anticipated or obvious in light of prior art. Further, the Federal Circuit cross-appeal filed by defendants in the original Delaware Action raises issues regarding the validity of the '681 and '553 patents that could be dispositive of PharmaStem's entire second wave of litigation. For example, defendants have raised on appeal the critical issue regarding the indefiniteness of the limitation in the '681 patent that requires that there be sufficient stem cells to reconstitute a human adult. Should the "adult" limitation be found to be indefinite on appeal, all claims of the newly asserted '681 patent, the entire '645 patent, and claims 49-56 of the '427 patent would be invalid. Further, a finding that the '681 and '553 patents are obvious in light of the Koike reference⁴ would invalidate all four patents, leaving no valid claims upon which PharmaStem could continue to litigate. Thus, the outcome of the appeal of the original Delaware Action could substantially alter or eliminate the claims involved in the consolidated cases.

(3) Reexamination

In addition, the PTO has granted reexamination regarding the '553, '645, and '427 patents.⁵ The PTO found that several references, particularly the Koike reference, raise a "substantial new question of patentability" regarding every claim of each of these patents. In

⁴ Koike, K. *Cryopreservation of Pluripotent and Committed Hemopoietic Progenitor Cells from Human Bone Marrow and Cord Blood*, Acte. Paeditr. Jpn., Vol. 25.3 (1983) ("Koike").

addition, regarding the '427 patent, the PTO ordered a second reexamination based on its finding that the "inventive entity of the '427 patent is identical to the inventive entity of the '681 patent" and therefore may create an obvious-type double patenting issue regarding claims 49-56 of the '427 patent. Thus, the validity of three of the four patents at issue in the consolidated cases is currently being reviewed by the PTO and any revisions that may be made to the claims in reexamination would substantially impact the consolidated cases.

(4) Collateral Estoppel / Issue Preclusion

As discussed above, all of the claims of the '645 patent and claims 49-56 of the '427 patent are substantially identical to those of the '681 patent, particularly in that they require a composition derived from umbilical cord blood from a single human that contains stem cells in "amount sufficient to effect hematopoietic reconstitution of a human adult." The question of whether or not the cord blood units stored by the defendant cord blood banks contained sufficient stem cells to reconstitute an adult was fully litigated in the original Delaware Action. Specifically, the Court ruled that "PharmaStem [had] failed to present evidence . . . that any specific cord blood unit or units stored by any of the defendants contained stem cells in a sufficient amount to reconstitute a human adult." 12/15/04 Memorandum at 8. Thus, pursuant to the doctrine of issue preclusion, PharmaStem is barred from relitigating this issue in the consolidated cases. Further, based on the Court's finding in the original Delaware Action that the cord blood banks did not infringe the '681 or the '553 patents, to the extent the claims at issue in the consolidated cases overlap with the claims at issue in the original Delaware Action, defendants assert that PharmaStem is barred by the doctrine of issue preclusion from arguing that the cord blood banks infringe such claims.

⁵ The reexamination order for the '681 patent was vacated but the reexamination applicants have

(5) Antitrust Violations/ Patent Misuse/ Unclean Hands

The cord blood banks, physicians, and healthcare providers further allege that PharmaStem's wrongful and exclusionary agreements and actions amount to patent misuse which violates federal antitrust laws, the federal Lanham Act, and various state laws regarding tortious interference with business relations and contracts, deceptive and unfair trade practices, and unfair competition. Through its false and misleading statements and its Amnesty Agreement Program, PharmaStem sought to coerce a boycott by physicians and healthcare providers of the private cord blood banks who refused to take a license from PharmaStem. PharmaStem's goal was to force private cord blood banks to accept unnecessary and overbroad licenses to certain PharmaStem patents, which would require the companies to pay royalties to PharmaStem even for non-infringing conduct. PharmaStem's anticompetitive campaign involved two steps. First, PharmaStem improperly asserted that any collection of cord blood by obstetricians or hospitals infringes its patents. Despite the fact that obstetricians and hospitals cannot incur liability under PharmaStem's patents merely by collecting umbilical cord blood, PharmaStem has sued numerous hospitals and physicians (not to mention private cord blood banks) for patent infringement. In addition, PharmaStem repeatedly made false and misleading public statements about its patents. This Court has already ruled that statements by PharmaStem in this regard were false and misleading, and enjoined PharmaStem from making future false and misleading statements. In defiance of the Court's order, PharmaStem sent letters to literally tens of thousands of physicians that contained inaccurate, false, and misleading assertions of patent infringement.

Second, after making its unsupportable infringement allegations and public

appealed this revocation.

misstatements, PharmaStem presented physicians and hospitals with what it calls an “Amnesty Agreement.” In these wrongful agreements, PharmaStem agrees to drop all claims and/or not to file suit if the physician or hospital agrees to a complete boycott of any private cord blood bank that has not signed one of PharmaStem’s wrongful licenses. The terms of these “Amnesty Agreements,” and the boycotts they impose, are far broader than any legitimate right to exclude PharmaStem may have from its patents, and thus violate the antitrust laws by seeking to unlawfully coerce a boycott of defendants.

As a result, PharmaStem’s conduct harmed defendants’ businesses. Physicians, healthcare providers, and even other cord blood banks have signed PharmaStem’s Amnesty Agreements or licenses in order to avoid the cost and burden of PharmaStem’s threatened litigation. Thus, PharmaStem’s misuse of its patents violates several federal and state laws designed to protect and encourage fair trade and competition.

(6) Patent Enforceability

In addition, pending the resolution of the reexaminations of the ‘553, ‘645 and ‘427 patents, the cord blood banks, physicians and healthcare providers further assert that they may be entitled to both absolute and equitable intervening rights should they be found to infringe any of the asserted patents.

Further, the cord blood banks, physicians, and healthcare providers have either asserted or preserved their right to assert that PharmaStem is precluded from enforcing its patents due to inequitable conduct before the PTO.

D. Other Related Actions

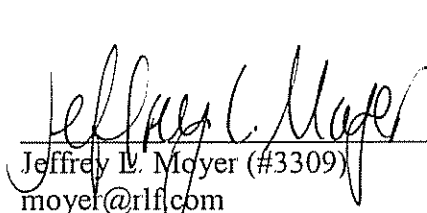
As discussed above, the appeal and cross-appeal of the original Delaware Action is currently pending before the Federal Circuit Court of Appeals.

E. Class Action Issues

The parties do not believe that there are any potential class action issues regarding the consolidated cases

F. Other Relevant Information

Defendants believe the most efficient and reasonable approach regarding the cases now before the Court would be to stay all discovery pending the decisions by the Federal Circuit and the PTO. PharmaStem, however, does not agree and would like to begin discovery regarding the physicians and healthcare providers before the appeal is resolved. Defendants' stance is based on the indisputable fact that the Federal Circuit's and/or the PTO's decision is likely to substantially change, or even to eliminate, any potential liability for defendants. The Federal Circuit decision, in particular, will set the ground rules for how this litigation should proceed, if at all. Defendants have already defended one case through trial, at enormous expense to these relatively modest companies. To begin discovery only to have the issues and claims change midway would be a waste of resources. In addition, without liability of the cord blood banks, the physicians and healthcare providers cannot be liable. Therefore, it is also unfair and inefficient to burden the physicians and healthcare providers now with the potentially unnecessary cost and effort of discovery, especially where the cord blood banks have successfully defended against PharmaStem's previous infringement claims.

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Dated: September 29, 2005

CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2005, I electronically filed the foregoing with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following who were also served as indicated below:

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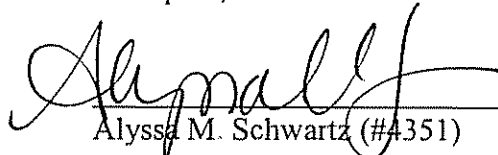
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